

ORAL ARGUMENT NOT YET SCHEDULED

Lead Case No. 24-1193
(Consolidated with Case Nos. 24-1261, 24-1266, 24-1271, and 24-1272)

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

CHAMBER OF COMMERCE OF THE
UNITED STATES OF AMERICA, et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY et al.,

Respondents,

and

CLEAN CAPE FEAR et al.,

Respondent-Intervenors,

*On Petition for Review of a Final Rule
of the U.S. Environmental Protection Agency*

**PROOF BRIEF OF RESPONDENT-INTERVENORS CLEAN CAPE FEAR,
ENVIRONMENTAL JUSTICE TASK FORCE, FIGHT FOR ZERO,
MERRIMACK CITIZENS FOR CLEAN WATER, AND NATURAL
RESOURCES DEFENSE COUNCIL**

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rules 27(a)(4) and 28(a)(1)(A), I certify that:

A. Parties and Amici: Except for the following, all parties, intervenors, and amici appearing in this court are listed in the Brief of Petitioners Chamber of Commerce et al. and Brief of Respondents Environmental Protection Agency et al.: State of New York, State of Colorado, The District of Columbia, Commonwealth of Massachusetts, State of Arizona, State of Connecticut, State of Illinois, State of Maryland, State of Michigan, State of Minnesota, State of New Jersey, State of New Mexico, State of Oregon, State of Washington, State of Wisconsin, all of which appear as Amici Curiae in support of Respondents.

B. Rulings Under Review: The ruling under review is EPA's Final Rule entitled "Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances," 89 Fed. Reg. 39,124 (May 8, 2024).

C. Related Cases: There are no related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

Dated: February 13, 2025

/s/ Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Clean Cape Fear, Environmental Justice Task Force, Fight for Zero, Merrimack Citizens for Clean Water, and Natural Resources Defense Council state that they are non-governmental, non-profit advocacy organizations dedicated to the protection of public health and the environment. They have no parent corporations and no publicly held corporation owns a 10% or greater ownership interest in these organizations.

Dated: February 13, 2025

/s/ Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz

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GLOSSARY

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act, Pub. Law No. 96-510, 94 Stat. 2767 (1980)
EPA	United States Environmental Protection Agency
Hazardous Substance Designations	Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 89 Fed. Reg. 39,124 (May 8, 2024)
PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances, a class of chemicals that includes PFOA and PFOS
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
RFA	Regulatory Flexibility Act

INTRODUCTION

Petitioners challenge the designation of two highly toxic and long-lasting chemicals as hazardous substances (the “Hazardous Substance Designations”) under the Comprehensive Environmental Response, Compensation, and Liability Act (“CERCLA”). These chemicals—perfluorooctanoic acid (“PFOA”) and perfluorooctanesulfonic acid (“PFOS”)—are part of the large class of per- and polyfluoroalkyl substances (“PFAS”), also known as “forever chemicals” because they can remain in the environment for centuries and build up in the bodies of animals and people. PFOA and PFOS contaminate communities across the country, including those where Intervenors’ members live, resulting in cancer, developmental harm, heart disease, and other severe effects.

Congress passed CERCLA to promote the cleanup of toxic chemicals like PFOA and PFOS. The law allows the Environmental Protection Agency (“EPA”) to undertake or to order the remediation of contaminated sites, while shifting the cost of remediating hazardous substances from the public to polluters and other responsible parties. CERCLA also authorizes EPA to designate hazardous substances that “may present substantial danger” to public health or the environment when released. 42 U.S.C. § 9602(a).

Unable to contest the substantial danger from PFOA and PFOS releases, Petitioners attempt to narrow the statutory standard for hazardous substance

designations. But their challenges to EPA's interpretation of "substantial danger" and to EPA's reasoned assessment of the designations' costs and benefits are inconsistent with CERCLA's text and contrary to Circuit precedent. And Petitioners' conjecture about the possibility of unsupported hazardous substance designations in the future does not, and cannot, refute the extensive record underlying the designations they challenge in this proceeding. Congress established a broad standard for the designation of hazardous substances, and PFOA and PFOS easily satisfy it. The Petitions should be denied.

Consistent with D.C. Circuit Rule 28(d)(2), Intervenors adopt the arguments in EPA's brief and supplement them as follows.

STATEMENT OF ISSUES

1. Whether EPA rationally determined that PFOA and PFOS "may present substantial danger to the public health or welfare or the environment" when released to the environment.

2. Whether EPA's assessment of the Hazardous Substance Designations' costs and benefits was arbitrary and capricious, when, even though CERCLA does not require such consideration, EPA voluntarily and rationally considered the designations' direct and indirect costs.

3. Whether EPA's acknowledgement that certain effects of the Hazardous Substance Designations cannot be precisely predicted renders the designations arbitrary and capricious.

STATUTES AND REGULATIONS

Pertinent statutes and regulations not provided with Petitioners' addendum (ECF No. 2083600) are provided in the accompanying addendum.

STATEMENT OF THE CASE

A. CERCLA

CERCLA "seeks to promote prompt cleanup of [contaminated] sites and to ensure that responsible parties foot the bill." *Gen. Elec. Co. v. Jackson*, 610 F.3d 110, 114 (D.C. Cir. 2010). "Unlike other environmental laws such as the Clean Air Act [and] Clean Water Act," however, "CERCLA is not a regulatory statute." *Pakootas v. Teck Cominco Metals*, 452 F.3d 1066, 1073 (9th Cir. 2006). Instead of restricting third-party conduct through national standards, CERCLA promotes the cleanup of contamination on a site-by-site basis by authorizing EPA to undertake or order such remediation. 42 U.S.C. §§ 9604, 9606(a). The statute also "creates a cause of action through which entities that have incurred costs" investigating or cleaning up hazardous substances "may sue to recover [such] costs from parties that may have played a role in causing the pollution, whom CERCLA refers to as

potentially responsible parties (PRPs).” *Lockheed Martin Corp. v. United States*, 833 F.3d 225, 227 (D.C. Cir. 2016); 42 U.S.C. § 9607(a).

Chemicals can be listed as hazardous substances under CERCLA in two ways. If a chemical is designated for regulation under certain other environmental laws—such as a hazardous air pollutant under the Clean Air Act or a toxic pollutant under the Clean Water Act—then it is automatically defined as a hazardous substance. 42 U.S.C. § 9601(14). There are approximately 800 hazardous substances that were designated in this manner, from sodium hypochlorite (bleach) and chlorine to mercury and dioxin. 40 C.F.R. § 302.4.

Additionally, CERCLA section 102(a) states that EPA “shall promulgate and revise as may be appropriate, regulations designating as hazardous substances ... such elements, compounds, mixtures, solutions, and substances which, when released into the environment may present substantial danger to the public health or welfare or the environment.” 42 U.S.C. § 9602(a). PFOA and PFOS are the first chemicals to be designated under that provision.

The designation of hazardous substances does not require any action by EPA or private parties aside from the reporting of releases above an assigned reporting threshold. *Id.* § 9603(a); *see also* Designation of PFOA and PFOS as CERCLA

Hazardous Substances, 89 Fed. Reg. 39,124, 39,131 (May 8, 2024), JA____.¹

Decisions about which sites to remediate and how to do so are made through subsequent administrative processes, “on a site-specific basis based on site-specific information.” Responses to Comments on Proposed Hazardous Substance Designations, EPA-HQ-OLEM-2019-0341-0839 at 116 (“Comment Responses”), JA____. Site remediation under CERCLA begins with a “remedial investigation” to “characterize the site ... [and] assess the risks to human health and the environment.” 40 C.F.R. § 300.430(d). This investigation is often coupled with a feasibility study that evaluates remedial options in light of the “site problems being addressed.” *Id.* § 300.430(e). Finally, to select the remedy for a given site, EPA weighs nine criteria, including costs, *id.* § 300.430(e)(9)(iii), and publishes a proposed remedial plan for public comment. *Id.* § 300.430(f)(2)-(3).

Similarly, decisions about who pays for remediation, and how much, are independent from the designation of a hazardous substance and made through site-specific settlements and third-party litigation. While liability under CERCLA is strict (without regard to fault) and broad by design, CERCLA authorizes EPA to enter settlements with individual parties that limit their third-party liability. 42

¹ Hazardous substance designations also impose limited requirements on certain other federal agencies. *See* 42 U.S.C. § 9620(h) (requiring agencies to provide notice when transferring property contaminated by hazardous substances); *id.* § 9656(a) (requiring Department of Transportation to update regulations to reflect hazardous substance designations).

U.S.C. § 9613(f)(2). When allocating costs among potentially responsible parties, courts consider “such equitable factors as the court determines are appropriate.” *Id.* § 9613(f)(1).

B. PFOA and PFOS

PFOA and PFOS are members of the large, widespread, and dangerous class of PFAS chemicals. PFAS are often called “forever chemicals” because their strong carbon-fluorine bonds “cause them to be extremely resistant to degradation and to remain in the environment for long periods of time.” 89 Fed. Reg. at 39,126, JA____. They do not occur naturally; PFAS were first manufactured in the 1940s for use in cookware, clothing, furniture, and other commercial and consumer products. *Id.* at 39,126, JA____. People born when PFAS were newly created now live in a world where they are virtually inescapable. Today, PFAS contaminate the drinking water supplies for tens of millions of people across the country and the blood of “nearly all of the participants” in a series of nationwide studies. *Id.* at 39,126, 39,148, JA____, ____; PFAS National Primary Drinking Water Regulation, 89 Fed. Reg. 32,532, 32,596 (Apr. 26, 2024), JA____.

The proliferation of PFAS has caused widespread harm. 89 Fed. Reg. at 39,127-28, JA____ - _____. Exposures to PFOA and PFOS are associated with cancer, decreased birth weight, increased cholesterol, liver damage, and reduced responsiveness to vaccines, among other serious conditions. *Id.* at 39,144-45,

JA____-____. EPA identified risks to children’s immune systems at the lowest measurable levels of PFOA and PFOS, meaning “any detectable level” places children’s health at risk. Earthjustice et al. Comments, EPA-HQ-OLEM-2019-0341-0458 at 3, JA____. Similarly, EPA found “no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk for either [PFOA or PFOS].” 89 Fed. Reg. at 32,564, JA____.

These risks are “exacerbated by the fact that PFOA and PFOS are persistent” and bioaccumulative, meaning even small releases can build up in the environment and in the bodies of people and animals. 89 Fed. Reg. at 39,126, 39,139, JA____, _____. Studies of workers and communities have found that people who are exposed to PFOA experience higher rates of thyroid disorders, decreased vaccination response, pregnancy-induced hypertension and preeclampsia, and multiple types of cancer. Health Effects Support Document for Perfluorooctanoic Acid (PFOA), EPA-HQ-OLEM-2019-0341-0187 at ES-1, JA____. Other human studies link PFOS exposure to high cholesterol, reproductive harm, and developmental harm. Health Effects Support Document for Perfluorooctane Sulfonate (PFOS), EPA-HQ-OLEM-2019-0341-0186 at ES-1-ES-2, JA____-____. In the early 2000s, after EPA publicly acknowledged both chemicals’ severe risks, “the principal worldwide manufacturers of PFOA and PFOS” largely “phased out” their production. Designation of Perfluorooctanoic Acid (PFOA) and

Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 87 Fed. Reg. 54,415, 54,417 (proposed Sept. 6, 2022), JA____, _____. However, both PFOA and PFOS remain “widespread ... in the environment.” 89 Fed. Reg. at 39,143, JA_____.

Intervenors represent communities that have been upended by PFOA and PFOS contamination. *See generally* Decls. in Supp. of Mot. to Intervene, ECF No. 2064064. In Tucson, Arizona, PFOA and PFOS releases from an airport and military bases contaminate the city’s drinking water and soil. *Id.* Decl. of Linda Shosie ¶¶ 4, 15. Linda Shosie, who has lived in the Tucson area for her entire life, lost her 19-year-old daughter and five-year-old niece to cancer, and her son, grandson, and neighbors have suffered from kidney disease and other ailments associated with PFAS exposure. *Id.* ¶ 5. In Winnabow, North Carolina, Emily Donovan’s drinking water comes from the Cape Fear River, a watershed with PFAS levels “among the highest in the nation” due to decades of discharges from a PFAS manufacturing plant upstream. *Id.* Decl. of Emily Donovan ¶¶ 1, 5-7. Many children in Ms. Donovan’s community have kidney cancer, and her “inner circle of friends and neighbors is filled with loved ones suffering from the trauma of cancer treatments, benign tumors, and terminal diagnoses.” *Id.* ¶ 11. On Florida’s Space Coast, Christel Bailey, her brother, her father, her uncle, and many others in their community have been diagnosed with cancer. *Id.* Decl. of Christel Bailey ¶ 2-3. In

2018, groundwater testing at a local military base revealed combined levels of PFOA and PFOS of up to 4.3 million parts per trillion (ppt) and levels in nearby residential areas of almost 500 ppt. *Id.* ¶ 9. EPA has found there is no safe level of either contaminant in drinking water. 89 Fed. Reg. at 32,564, JA _____. And in Merrimack, New Hampshire, discharges from a nearby PFAS manufacturing plant contaminate the groundwater that Laurene Allen and 29,000 other residents use for drinking, cooking, and bathing. Decls. in Supp. of Mot. to Intervene, Decl. of Laurene Allen ¶¶ 6, 9. At a crowded public meeting where state officials announced the closure of wells due to serious health risks, many “came forward to disclose serious health concerns—including diagnoses with various cancers and thyroid problems.” *Id.* ¶ 7, 10. These experiences are tragically common; PFOA and PFOS “threaten communities across the country,” and their “mobility and persistence combine to create an ever-expanding area of contamination.” 89 Fed. Reg. at 39,148, 39,152, JA _____, _____.

C. The Hazardous Substance Designations

In September 2022, EPA proposed to designate PFOA and PFOS as hazardous substances under CERCLA section 102(a). 87 Fed. Reg. at 54,415, JA _____. In May 2024, EPA finalized those designations. 89 Fed. Reg. 39,124, JA _____.

1. EPA's Assessment and Determination of "Substantial Danger"

Because it had not previously designated hazardous substances under section 102(a), EPA set forth a multi-factor standard "for determining what constitutes 'substantial danger'" under that section. 89 Fed. Reg. at 39,141-43, JA ____ - ____.

EPA identified two "primary" factors: "[1] the potential harm to humans or the environment from exposure to the substance (i.e., hazard)," and "[2] how the substance potentially moves, persists and/or changes when in the environment (i.e., environmental fate and transport)." *Id.* at 39,141, JA ____.

EPA also considered "additional information that could inform the degree of danger a substance may pose when released," including the "prevalence" of the substance and the "likelihood of human exposure." *Id.*, JA ____.

When applying those factors to PFOA and PFOS, EPA evaluated studies on the chemicals' hazards, persistence, and mobility, as well as environmental monitoring and human biomonitoring data on the extent of their exposures. *Id.* at 39,143-48, JA ____ - ____.

Based on the evidence of their severe health effects, "extreme[]" resistanc[ce] to degradation," "high[]" mobil[ity], and "widespread" detections in humans and the environment, EPA found that releases of PFOA and PFOS "may present substantial danger to public health or welfare or the environment." *Id.* at 39,125-26, JA ____ - ____.

2. EPA's Consideration of the Designations' Costs

In the proposed designations, EPA “propose[d] to interpret CERCLA section 102(a) as excluding consideration of cost in a designation decision.” 87 Fed. Reg. at 54,423, JA____. However, pursuant to various executive orders, EPA prepared an Economic Assessment of the designations' costs and benefits. *Id.* at 54,439, JA____. That assessment quantified the designations' direct costs (i.e., increased reporting of PFOA and PFOS releases). Economic Assessment, EPA-HQ-OLEM-2019-0341-0035 at 39-77, JA____ - _____. It also included a qualitative assessment of the indirect costs, such as future site remediation, which are not required by the designations but rather depend upon separate, site-specific decisions that EPA could not predict. *Id.* at 45-57. JA____ - _____. EPA solicited comment on its Economic Assessment, including a request for “information ... that may allow EPA to estimate incremental indirect costs.” *Id.* at 19, JA_____.

Multiple parties, including several of the Petitioners, submitted comments on the potential costs of PFOA and PFOS remediation and associated litigation. *See, e.g.,* Chamber of Commerce et al. Comments, EPA-HQ-OLEM-2019-0341-0569 at 45-50 (“Chamber Comm.”), JA____ - _____. EPA responded to those comments, explaining that the designations “do[] not require any response action by a private party ... [or] determine liability for hazardous substance release response costs,” and that the costs described in the comments were “contingent upon a series of separate,

discretionary actions.” Comment Responses at 7, JA____. As requested in Petitioners’ comments, EPA also “expanded its economic assessment” in the final designations’ Regulatory Impact Analysis, which includes “illustrative” estimates of indirect costs and benefits. 89 Fed. Reg. at 39,179, 39,181, JA____, ____.

In the final rule, EPA found that the Hazardous Substance Designations are justified based on the “substantial danger” analysis set forth in EPA’s proposal. 89 Fed. Reg. 39,143, JA____. Without deciding whether CERCLA section 102(a) requires the consideration of costs, EPA conducted a “totality of the circumstances” analysis that “confirmed EPA’s conclusion that designation is warranted” even if costs were considered. *Id.* at 39,126, JA____.

SUMMARY OF ARGUMENT

If any chemicals satisfy CERCLA’s standard for designation as hazardous substances, they are PFOA and PFOS. They are highly toxic at the lowest measurable exposure levels, quick to spread through the environment and slow to break down. Petitioners do not dispute the extensive evidence of these chemicals’ harms or deny that PFOA and PFOS “may present substantial danger to the public health or welfare or the environment.” 42 U.S.C. § 9602(a). Instead, they contrive new limits on EPA’s authority and allege procedural violations that have no basis in CERCLA or this Circuit’s precedent.

1. EPA's interpretation of "may present substantial danger" accords with the statute's broad text and well-established administrative law. EPA identified factors that are undisputedly relevant to that statutory standard and rationally applied them to the facts. Despite Petitioners' claims, nothing in CERCLA requires a more prescriptive or narrower definition. Nor is there any statutory conflict, much less a constitutional concern, raised by EPA's designation of two highly persistent and widespread carcinogens as hazardous substances.

2. EPA's assessment of the designations' costs and benefits is also rational and supported by the record. Contrary to Petitioners' claim, CERCLA does not require EPA to consider costs when designating hazardous substances. Here, EPA did so voluntarily, providing further support for a decision that is justified without any cost analysis.

Petitioners had ample opportunity to comment on the designations' costs and benefits, and many of them did just that. The Administrative Procedure Act ("APA") does not entitle Petitioners to an additional round of comment on the illustrative cost estimates that EPA prepared in response to Petitioners' comments and that are not needed to support the Hazardous Substance Designations. Petitioners' challenges to those estimates misrepresent the effects of the designations, misstate relevant facts, and cannot overcome the substantial deference owed to agencies' cost calculations. And Petitioners' demand for

additional review under the Regulatory Flexibility Act fails because only significant *direct* impacts, not indirect impacts dependent on third parties or separate administrative actions, can trigger such review.

3. Finally, the absence of certainty surrounding some of the designations' downstream effects does not prevent EPA from acting to address PFOA and PFOS's known risks. As this Court has recognized, predictions of regulatory impacts are inherently uncertain, particularly where, as here, the impacts are contingent upon future, third-party actions. In the Hazardous Substance Designations, EPA appropriately acknowledged areas of uncertainty and explained why they did not change EPA's finding that PFOA and PFOS satisfy the standard for designation.

STANDARD OF REVIEW

Intervenors incorporate the standard of review from EPA's brief.

ARGUMENT

I. EPA Rationally Determined PFOA and PFOS Releases “May Present Substantial Danger” to Health, Welfare, or the Environment

A. CERCLA gives EPA broad discretion in designating hazardous substances

The “best reading” of section 102(a) is that it gives EPA broad authority to designate hazardous substances. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 371 (2024).

CERCLA’s language is broad on its face: EPA may designate substances as hazardous if, when released, they “may present substantial danger to the public health or welfare or the environment.” 42 U.S.C. § 9602(a). “Congress could have limited [EPA’s] discretion in any number of ways,” including by providing a statutory definition of substantial risk or “an exhaustive or illustrative list” of factors that EPA had to consider. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 676 (2020). But it “chose not to do so,” *id.* at 677, opting instead to grant EPA “broad discretion in designating substances which may adversely affect public health or the environment.” S. Rep. No. 96-848 at 28 (1980). The Hazardous Substance Designations are well within CERCLA’s delegation of authority.

Petitioners’ arguments to the contrary lack merit. To argue that EPA must provide “fix[ed] boundaries” on its interpretation of “may present substantial danger,” Petitioners point to stray language from *Loper Bright* divorced from its context and the holding of that case. Pet’rs’ Br. at 30. The language Petitioners quote describes the courts’ role in policing the *constitutional* boundaries of congressional delegation; it does not support Petitioners’ argument that agency interpretations of their authority must articulate bright-line boundaries. *Loper Bright*, 603 U.S. at 395 (courts “effectuate the will of Congress subject to constitutional limits ... [by] ‘fix[ing] the boundaries of the delegated authority.’”).

Indeed, in the same part of the opinion, *Loper Bright* recognizes that sometimes “the best reading of a statute is that it delegates discretionary authority to an agency,” such as when the statute “empower[s] an agency ... to regulate subject to the limits imposed by a term or phrase that ‘leaves agencies with flexibility.’” *Id.* Such is the case here.

Petitioners’ reliance on *ACA Int’l v. FCC*, 885 F.3d 687 (D.C. Cir. 2018) is similarly misplaced. Pet’rs’ Br. at 31. *ACA* does not stand for a general principle that broad interpretations “are ‘incompatible with congressional intent.’” *Id.* Rather, *ACA* held that an anti-telemarketing statute could not be interpreted to prohibit “ordinary calls from any conventional smartphone” because it would lead to “anomalous outcomes” that are “incompatible with” the aims of the statute. *Id.* at 692, 697-98. In contrast, the Hazardous Substance Designations are entirely consistent with CERCLA’s purpose to clean up releases of substances that endanger health and the environment. Despite contending that EPA “impermissibly lowers the bar set by Congress,” Petitioners offer neither an affirmative reading of what they believe that bar is, nor any evidence that CERCLA’s text, structure, or purpose preclude EPA’s approach. Pet’rs’ Br. at 33; *see infra* pp. 22-24 (addressing Petitioners’ statutory structure arguments).

Unable to contest the broad language of section 102(a), Petitioners mischaracterize EPA’s designation approach as “a blank check.” Pet’rs’ Br. at 32.

It isn't. EPA explained in the Hazardous Substance Designations that whether a substance "may present substantial danger" depends on factors including the substance's hazard, environmental fate and transport, and the frequency, nature, and geographic scope of releases. 87 Fed. Reg. 54,421, JA____. Each of those factors, by the definitions of those terms, imposes "real boundaries" on EPA's discretion. *See* Pet'rs' Br. at 31; EPA Br. at 32 ("Petitioners ... fail to acknowledge the constraints inherent in EPA's approach."). EPA's detailed analysis of the real-world dangers associated with PFOA and PFOS—encompassing a thorough review of the scientific literature and extensive monitoring data—would have been wholly unneeded if any "remote possibility of harm" satisfied EPA's standard. Pet'rs' Br. at 33; 89 Fed. Reg. 39,143-48, JA____-____. As for Petitioners' speculation that EPA may designate less harmful materials as hazardous substances in the future, Petr's' Br. at 32-33, "the theoretical possibility that an agency might someday abuse its authority is of limited relevance in determining whether the agency's interpretation of a congressional delegation is reasonable." *PDK Lab'ys Inc. v. U.S. Drug Enft Admin.*, 438 F.3d 1184, 1192 (D.C. Cir. 2006).

Petitioners' arguments that EPA acted beyond its broad statutory authority fail because they ask the Court to read requirements into section 102(a) that are not there. "It is a fundamental principle of statutory interpretation that 'absent provision[s]' cannot be supplied by the courts," and Petitioners cannot ask the

Court to “impos[e] limits on an agency’s discretion that are not supported by the text.” *Little Sisters of the Poor*, 591 U.S. at 677.

B. EPA’s multi-factor approach is reasonable and consistent with this Court’s precedent

In addition to lacking textual support, Petitioners’ demands for a “more definite standard” involving “concrete, quantitative thresholds,” Pet’rs’ Br. at 37, are contrary to well-established administrative law and this Court’s precedent.

Neither CERCLA nor the APA requires EPA to provide an exhaustive definition of “may present substantial danger” or to delineate the outer limits of that phrase in a vacuum. Rather, EPA is “entitled to proceed case by case” and “establish the term’s contours through a series” of designations, as opposed to “issu[ing] a comprehensive definition all at once.” *PDK Lab ’ys*, 438 F.3d at 1194-95. When interpreting an “open-ended term” like substantial danger, EPA “must simply define and explain the criteria the agency is applying.” *Catawba Cnty. v. EPA*, 571 F.3d 20, 39 (D.C. Cir. 2009); *PDK Lab ’ys*, 438 F.3d at 1194.

Here, EPA did just that. *See supra* pp. 9-10. EPA identified and defined the factors it considered: hazard; environmental fate and transport; and the frequency, nature, and geographic scope of releases. *See* 89 Fed. Reg. at 39,141, JA____ (defining “hazard” to include “carcinogenicity, neurotoxicity, developmental toxicity, reproductive toxicity, and other adverse health effects”); *id.* (defining “fate and transport” as “how the substance potentially moves, persists and/or changes

when in the environment”). EPA’s detailed analysis of PFOA and PFOS’s severe hazards, high persistence, and widespread exposures explain why each factor supports the Hazardous Substance Designations. *Id.* at 39,143-48; 39,163, JA____ - ____; ____; *see also infra* pp. 20-22.

EPA’s approach is necessarily flexible given the nature of weighing different types of evidence under CERCLA’s broad statutory standard. *See* EPA Br. 37-38; 89 Fed. Reg. 39,166, JA____ (explaining that a bright-line standard is not practicable in part because of inherent complexities in risk analysis). “Agencies routinely employ multi-factor standards,” and this Court has “never hesitated” to uphold such approaches where, as here, the underlying decision is “adequately explained.” *PDK Lab’ys*, 438 F.3d at 1194; *see also Catawba Cnty.*, 571 F.3d at 39 (“An agency is free to adopt a totality-of-the-circumstances test to implement a statute that confers broad discretionary authority, even if that test lacks a definite ‘threshold’ or ‘clear line of demarcation to define an open-ended term.’”).

For instance, this Court has upheld EPA’s finding that leaded gasoline “will endanger the public health or welfare” based on a totality-of-the-evidence analysis without requiring a formula with which EPA considered the relevant factors. *Ethyl Corp. v. EPA*, 541 F.2d 1, 44 (D.C. Cir. 1976) (“will endanger” denotes a “precautionary standard that embraces a wide range of permissible proof.”). This Court has also upheld agency actions based on non-exhaustive sets of factors. *See.*,

e.g., *Nat. Res. Def. Council v. EPA*, 25 F.3d 1063, 1069-70 (D.C. Cir. 1994) (upholding multi-factor balancing test, included the open-ended consideration of “such other factors as may be appropriate,” as “reasonable and consistent with the broad discretion afforded by the regulatory language.”); *Lomak Petroleum v. FERC*, 206 F.3d 1193, 1196 (D. C. Cir. 2000) (upholding the FERC’s application of a multi-factor test where “[n]o one factor is determinative ... and not all factors apply in all situations.”).

EPA’s multi-factor approach is at home among the other multi-factor tests upheld by this Court because “[n]othing in the statutory mandate required greater specificity.” *See Animal Legal Def. Fund. v. Glickman*, 204 F.3d 229, 235 (D.C. Cir. 2000); *see also Shays v. Fed. Election Comm’n*, 528 F.3d 914, 930 (D.C. Cir. 2008).

C. EPA rationally concluded, from a wealth of evidence, that PFOA and PFOS “may present substantial danger”

Tellingly, despite their challenges to EPA’s interpretation of “substantial danger,” Petitioners do not deny that PFOA and PFOS “may present substantial danger to the public health or welfare” when released. Nor could they—EPA’s review of the extensive literature on PFOA and PFOS’s hazards, fate and transport, and exposures readily demonstrates that these substances satisfy that standard under any reasonable reading of section 102(a). 89 Fed. Reg. 39,143-48, JA____ -

____. PFOA and PFOS represent, according to public health professionals, “one of the most seminal public health challenge[s] for the next decades.”²

On hazards posed by PFOA and PFOS, EPA reviewed scores of studies showing that exposure to these substances can lead to adverse health effects, including multiple cancers, developmental effects to fetuses and infants, immune effects, and liver damage. 89 Fed. Reg. 39,143-46, JA _____ - _____. Epidemiological studies show that current levels of PFOA and PFOS exposures are already contributing to these harms. *Id.* at 39,144-45, JA _____ - ____.

On fate and transport, EPA found that PFOA and PFOS are extraordinarily mobile and persistent in the environment: they move “easily” between environmental media and are “extremely resistant to degradation,” meaning “the potential for human exposure continues long after a release has ended.” 89 Fed. Reg. 39,147-48, JA _____ - _____. Once people are exposed, PFOA and PFOS “remain in the human body for ... long durations,” resulting in “elevated concentrations of [PFOA and PFOS]” in “individuals who have consistent ongoing exposures.” 89 Fed. Reg. 39,126, JA _____.

² UNEP, Report of the Persistent Organic Pollutants Review Committee on the Work of its Fourteenth Meeting: Addendum to the Risk Management Evaluation on Perfluorooctanoic Acid (PFOA), EPA-HQ-OLEM-2019-0341-0113 at 46, JA _____ (quoting Patrick Breyse, Director of the CDC’s National Center for Environmental Health).

On the scope of exposure and releases, EPA found a likelihood of human and environmental exposure to PFOA and PFOS through “a variety of sources, including water, food, and environmental media.” 89 Fed. Reg. 39,147, JA____. Samples taken every two years since 1999 have shown more than 95% of the U.S. population over the age of 12 has detectable levels of PFOA and PFOS in their blood. 89 Fed. Reg. 39,149, JA____.³

Given the overwhelming scientific evidence of their toxicity, persistence, and prevalence, EPA rationally concluded that PFOA and PFOS “may present substantial danger to the public health or welfare or the environment.” 42 U.S.C. § 9602(a).

D. EPA’s interpretation of substantial danger is consistent with CERCLA’s statutory structure and EPA’s interpretation of other provisions

Petitioners’ claim that EPA’s approach to hazardous substance designation subverts CERCLA’s statutory structure misrepresents how the statute treats hazardous substances compared to “pollutants or contaminants.” Pet’rs’ Br. at 35. “Hazardous substances” and “pollutants or contaminants” play complementary but distinct roles under the statute. Hazardous substances are designated via a rulemaking process that evaluates their potential to cause harm, either under

³ Samples have been taken every two years with the exception of 2001-2002. 89 Fed. Reg. 39,148, JA____.

CERCLA or a cross-referenced statute, so EPA may remediate them without any further factual findings. 42 U.S.C. §§ 9601(14), 9604(a)(1). By contrast, EPA identifies pollutants and contaminants without rulemaking on a *site-specific* basis, and EPA may only clean up pollutants and contaminants if the agency demonstrates their presence at a particular site poses an “imminent and substantial danger to the public health or welfare.” *Id.* § 9604(a)(1); 89 Fed. Reg. at 39,173, JA____ (“[A] substance’s status as a pollutant or contaminant is determined on a site-specific basis.”). Contrary to Petitioners’ assertion, hazardous substances are not meant to be a “smaller category” than “pollutants or contaminants” because the latter is not a fixed list of substances at all. Pet’rs’ Br. at 36.

Petitioners are also wrong that the statutory definition of “pollutant or contaminant” reflects “an easier standard to satisfy than the standard for ‘hazardous substances.’” Pet’rs’ Br. at 36 (emphasis removed).⁴ The fact that EPA has broader authority to remediate hazardous substances compared to pollutants or contaminants does not mean the latter are inherently less dangerous. Indeed, prior to the Hazardous Substance Designations, EPA conducted cleanup of PFOA and

⁴ CERCLA defines “pollutant or contaminant” to “include, *but not be limited to*, [substances] which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, ... will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.” 42 U.S.C. § 9601(33).

PFOS as pollutants and contaminants. 89 Fed. Reg. 39,173, JA____. “Pollutants or contaminants” exists as a residual category because Congress recognized that some substances pose an imminent and substantial danger at a particular site even though they have not been designated as hazardous substances. The “statutory hierarchy” between hazardous substances and pollutants or contaminants is Petitioners’ construct, not Congress’s. Pet’rs’ Br. at 35.

E. EPA’s interpretation raises no constitutional concerns

CERCLA provides an “intelligible principle” to guide EPA’s designation of hazardous substances and is thus a constitutional delegation of authority under longstanding Supreme Court precedent. *See* Pet’rs’ Br. at 34. Time and time again, the Supreme Court has upheld delegations of authority far broader than CERCLA section 102(a). *E.g.*, *Nat’l Broad. Co. v. United States*, 319 U.S. 190, 215-16 (1943) (requiring agency to act in the “public interest”); *Whitman v. Am. Trucking Ass’n*, 531 U.S. 457, 472-76 (2001) (requiring promulgation of standards “requisite to protect the public health.”). “In light of these precedents, one cannot plausibly argue that” section 102(a) does not provide an intelligible principle. *Touby v. United States*, 500 U.S. 160, 165 (1991).

Equally unpersuasive is Petitioners’ claim that EPA’s approach contravenes due process because it fails to provide notice as to “what EPA might designate next.” Pet’rs’ Br. at 34. This is a contrived notion of due process, which does not

require the ability to predict all actions that could flow from agency authority. Rather, agencies satisfy due process notice requirements if, “by reviewing the regulation[.]... a regulated party acting in good faith would be able to identify, with ‘ascertainable certainty,’ [how] the agency expects parties to conform.” *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1329 (D.C. Cir. 1995). EPA clearly and comprehensively articulated the legal obligations imposed by the Hazardous Substance Designations, 89 Fed. Reg. 39,131-32, JA____ - __, so due process is satisfied.

II. While Not Required by CERCLA Section 102, EPA Rationally Assessed the Costs and Benefits of the Hazardous Substance Designations

Petitioners claim that EPA violated CERCLA, and acted arbitrarily and capriciously, by failing to consider the costs associated with the Hazardous Substance Designations. Pet’rs’ Br. at 39-44. This argument fails for two reasons. First, nothing in CERCLA compels EPA to consider costs when designating hazardous substances.⁵ Second, even if such consideration was required, here EPA lawfully evaluated the costs and benefits of the Hazardous Substance Designations, and its reasoned assessment of those costs warrants deference.

⁵ Intervenor’s agree with EPA that the Court does not need to reach this issue to uphold the Hazardous Substance Designations. *See* EPA Br. at 39. To the extent the Court considers it, however, Petitioners’ misinterpretation of CERCLA section 102(a) provides an additional basis for rejecting the petition and upholding the Hazardous Substance Designations.

A. CERCLA section 102(a) does not require EPA to consider costs

“When ‘addressing a question of statutory interpretation, we begin with the text.’” *Pac. Gas & Elec. Co. v. FERC*, 113 F.4th 943, 948 (D.C. Cir. 2024). CERCLA section 102(a) provides that EPA “shall promulgate and revise as may be appropriate, regulations designating as hazardous substances ... such ... substances which, when released into the environment may present substantial danger to the public health or welfare or the environment.” 42 U.S.C. § 9602(a). That provision does not require EPA to consider costs when making hazardous substance designations. Rather, “the statute meant what it said,” *Me. Cmty. Health Options v. United States*, 590 U.S. 296, 311 (2020): EPA’s designation of hazardous substances rests on whether a substance, when released, may present substantial danger to public health, welfare, or the environment.

The Supreme Court has held that the determination of a chemical’s danger to public health and welfare does not include the consideration of costs. For example, the Clean Air Act directs EPA to set National Ambient Air Quality Standards “requisite to protect the public health,” with an “adequate margin of safety.” 42 U.S.C. § 7409(a)(1)-(b)(1). In *Whitman v. American Trucking*, the Court found it “fairly clear that this text does not permit the EPA to consider costs in setting the standards,” but rather called for a scientific determination based on a pollutant’s “health effects.” 531 U.S. 457, 465 (2001); *see also A Cmty. Voice v. EPA*, 997 F.3d

983, 990-92 (9th Cir. 2021) (statutory requirement to identify lead-based paint hazards that present “adverse human health effects” prohibits the consideration of costs). Here too, Congress directed EPA to designate hazardous substances based on whether they “may present substantial danger” to human health and the environment.

That interpretation is supported by CERCLA’s statutory structure, which defers the consideration of costs until the remedy selection process when EPA is better positioned to estimate costs and benefits. *See, e.g.*, 42 U.S.C. § 9621(a) (requiring EPA to consider “short- and long-term costs” when selecting the remedy for a given site). The express mandate for cost considerations in other provisions of CERCLA “shows that Congress knew how to” impose such a requirement “when it wanted to.” *Chicago v. Env’t Def. Fund*, 511 U.S. 328, 338 (1994); *Whitman*, 531 U.S. at 467 (refusing to “find implicit in ambiguous sections of the CAA an authorization to consider costs that has elsewhere ... been expressly granted.”).

Petitioners’ argument that section 102(a) compels the consideration of costs rests on a misreading of *Michigan v. EPA*, 576 U.S. 743 (2015). *Michigan* held that Clean Air Act section 111(n)—which directs EPA to “regulate emissions of hazardous air pollutants from power plants if the Agency finds regulation ‘appropriate and necessary’”—“requires at least some attention to cost.” *Id.* at 747, 752 (quoting 42 U.S.C. § 7412(n)(1)(A)). Petitioners contend that, because CERCLA section 102(a) requires EPA to promulgate and update its list of

hazardous substances “as may be appropriate,” it too compels EPA to consider costs. Pet’rs’ Br. at 40-41.

Michigan, however, makes clear that the meaning of “appropriate” is determined by context, and “there are undoubtedly settings in which the phrase ‘appropriate and necessary’ does not encompass cost.” 576 U.S. at 752; *see also Sossamon v. Texas*, 563 U.S. 277, 286 (2011) (“[T]he word ‘appropriate’ is inherently context dependent.”). This Court has “rejected the idea that ‘appropriate’” necessarily “requires consideration of economic costs.” *Murray Energy Corp. v. EPA*, 936 F.3d 597, 622 (D.C. Cir. 2019) (holding that EPA was neither required nor permitted to consider costs when determining whether revisions to ambient air quality standards “may be appropriate.”).

The Supreme Court’s decision in *Michigan* turned not on a singular definition of “appropriate,” but rather on the text and structure of Clean Air Act section 112(n). *See* 576 U.S. at 752-53; *accord Murray Energy*, 936 F.3d at 622. In both respects, that provision is distinguishable from CERCLA section 102(a).⁶

⁶ Contrary to Petitioners’ claims, *Alon Refin. Krotz Springs. v. EPA*, 936 F.3d 628 (D.C. Cir. 2019), did not “require [EPA] to consider cost” when determining whether to make renewable fuel requirements “applicable to refineries, blenders, and importers, as appropriate.” Pet’rs’ Br. at 42-43. *Alon* merely held that EPA was not required to make that applicability determination on an annual basis; this Court did not address the role of costs in that decision. 936 F.3d at 654-55.

First, Clean Air Act section 112 requires EPA to study “the costs of” reducing power plant mercury emissions, 42 U.S.C. § 7412(n)(1)(B), and to consider the results of that study, among others, when determining whether the regulation of power plants is “appropriate and necessary.” *Michigan*, 576 U.S. at 753. The Supreme Court cited that required study as an “indication of the relevance of cost to the decision to regulate.” *Id.* But there is no comparable provision of CERCLA section 102, which does not mention costs, much less require EPA to study the costs of hazardous substance designations. *See* 42 U.S.C. § 9602(a).

Second, the decision to regulate power plants under Clean Air Act section 112(n) rests exclusively on a finding that such regulation is “appropriate and necessary.” 42 U.S.C. § 7412(n)(1)(A). The Court in *Michigan* distinguished that “capacious” grant of authority from Clean Air Act section 109(b), where Congress “requir[ed] EPA to set ambient air quality standards at levels ‘requisite to protect the public health’ with an adequate margin of safety.” *Michigan*, 576 U.S. at 755. Like Clean Air Act section 109(b), CERCLA section 102(a) requires EPA to find that a substance “may present substantial danger” to public health, welfare, or the environment before EPA can designate it as a hazardous substance. 42 U.S.C. § 9602(a). That substantive standard, which is lacking in Clean Air Act section 112(n), provides the context for when such designations “may be appropriate.” *Id.*; *see also* S. Rep. No. 96-848 at 28 (“[CERCLA] authorizes the President to

designate as hazardous substances those compounds ... which may present substantial danger to public health and welfare and the environment.”).

Petitioners acknowledge that determining “whether a substance *is* hazardous”—that is, whether it may present a substantial danger to health or the environment—“[a]rguably ... does not require EPA to consider costs.” Pet’rs’ Br. at 43 (emphasis in original). Yet they attempt to read a cost-consideration requirement into “appropriate” that is not there, ignoring *Michigan*’s instruction that “the relevant factors” encompassed by the term “appropriate” depend on statutory text and context. *See Michigan*, 576 U.S. at 752. In the context of CERCLA section 102(a), “appropriate” authorizes EPA to consider factors that are relevant to the protection of public health, welfare, and the environment. For instance, if a chemical presents substantial danger when released to the air but is not present in soil or water, EPA may find that designation is not appropriate because it would not address the substance’s danger or promote CERCLA’s remedial objectives. It also “may be appropriate” for EPA to “revise” its hazardous substance designations if a previously designated substance is later found not to present a substantial danger to health, welfare, or the environment. 42 U.S.C. § 9602(a). But “appropriate” cannot be read to compel the consideration of factors unrelated to CERCLA’s standard for hazardous substance designations, including costs. *See Murray Energy Corp.*, 936 F.3d at 622; *Kennecott Greens Creek Mining*

Co. v. Mine Safety & Health Admin., 476 F.3d 946, 960-61 (D.C. Cir. 2007)

(rejecting the argument that OSHA must conduct a cost-benefit analysis when determining whether work medical evaluations were “appropriate”).⁷

A. EPA rationally evaluated the costs and benefits of the Hazardous Substance Designations

While it was not required to do so, EPA considered the Hazardous Substance Designations’ costs in both its proposed and final rule. The assessment of costs and benefits “epitomize[s] the types of decisions that are most appropriately entrusted to the expertise of an agency.” *Nat’l Ass’n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) (citation omitted); *Charter Commc’ns v. FCC*, 460 F.3d 31, 42 (D.C. Cir. 2006). Courts therefore “review[] cost-benefit analyses deferentially,” and Petitioners’ “burden to show error is high.” *Cigar Ass’n of Am. v. Food & Drug Admin.*, 5 F.4th 68, 76 (D.C. Cir. 2021); *Nat’l Wildlife Fed’n v. EPA*, 286 F.3d 554, 563 (D.C. Cir. 2002). Petitioners fail to carry that burden.

1. Petitioners had notice of and opportunity to comment on EPA’s cost analysis

Despite Petitioners’ claims, EPA did not “fail[] to disclose its analysis of costs until promulgating the [Hazardous Substance Designations],” Pet’rs’ Br. at

⁷ While the Court may review EPA’s voluntary assessment of costs and benefits, Petitioners’ arguments that such analysis is “critical” to the Hazardous Substance Designations, Pet’rs’ Br. at 51, or that the alleged errors in that analysis are not harmless, *id.* at 50, ring hollow when EPA was not required to consider costs in the first instance.

40, or “deprive[] the public” of the “opportunity to meaningfully comment on the costs and benefits of the Rule.” Nat’l Ass’n of Mfrs. Amicus Br. at 6. Instead, the Economic Assessment included with the proposed Hazardous Substance Designations quantifies their direct costs and qualitatively evaluates their benefits and indirect costs. Economic Assessment at 39-48, JA ____ - ____ . As EPA explains, the costs that Petitioners focus on are not required by the Hazardous Substance Designations, but are instead contingent upon subsequent independent administrative acts, site-specific clean-up decisions, and potential third-party litigation. 89 Fed. Reg. at 39,128 n.9, 39,160, JA ____, ____ . Agencies are permitted and, indeed, encouraged to assess such costs and benefits qualitatively, particularly when faced with uncertainties that make quantification impracticable. *Mozilla Corp. v. FCC*, 940 F.3d 1, 70 (D.C. Cir. 2019); OMB Circular No. A-4: Regulatory Analysis at 5 (Nov. 9, 2023).

When soliciting comment on its proposal, EPA requested information related to “[EPA’s] approach to the consideration of costs,” 87 Fed. Reg. at 54,423, JA ____, including “uncertainties regarding the unquantifiability of indirect cost, benefit, and transfer impacts” and “information ... that may allow EPA to estimate incremental indirect costs associated with this rule.” Economic Assessment at 19, JA ____ . Indeed, multiple Petitioners submitted detailed comments on the

designations' alleged costs.⁸ EPA responded to those comments, explaining why Petitioners' estimates were overstated or unsupported by the record. *E.g.*, Comment Responses at 119-22, 221-23, 289, JA ____ - __, ____ - __, ____; *see also* EPA Br. at 58-59, 61-63. As requested in Petitioners' comments, EPA also "expanded its economic assessment" in a Regulatory Impact Analysis, which includes "illustrative" examples of indirect costs and benefits. 89 Fed. Reg. at 39,179; JA ____; EPA, Regulatory Impact Analysis, EPA-HQ-OLEM-2019-0341-0835 at 27, 160 ("RIA"), JA ____, ____.

Petitioners' claim that EPA was required to reopen the comment period for that Regulatory Impact Analysis fails for two reasons. First, EPA's proposed designations and Economic Assessment provide "an adequate foundation for comment" on the designations' costs and benefits, including the elements of the cost analysis that EPA expanded in the final designations. *City of Stoughton. v. EPA*, 858 F.2d 747, 753 (D.C. Cir. 1988). Petitioners answered EPA's call for comments, EPA took their comments into account, and the Regulatory Impact Analysis released with the final designations is a logical outgrowth of that process.

⁸ *See e.g.*, Chamber Comm. at 45-50, JA ____ - __; American Chemistry Council Comments, EPA-HQ-OLEM-2019-0341-0421 at 7 ("ACC Comm."), JA ____; Associated General Contractors Comments, EPA-HQ-OLEM-2019-341-0418 at 7-8 ("AGC Comm."), JA ____ - __; Chamber of Commerce Cost Analysis, EPA-HQ-OLEM-2019-341-0405 ("COC Cost Analysis"), JA ____; National Waste and Recycling Association Comments, EPA-HQ-OLEM-2019-341-0480 at 2-3 ("NWRA Comm."), JA ____ - __.

Second, the cost estimates in the analysis were not “critical” to the Hazardous Substance Designations, but were rather a supplementary analysis that “did no more than provide support for the same decision [EPA] had proposed to take.” *Int’l Fabricare Inst. v. EPA*, 972 F.2d 384, 399 (D.C. Cir. 1992). Under this Circuit’s precedent, such supplementary material does not provide a basis for reopening the comment period. *Id.*

To start, the APA does not “automatically generate a new opportunity for comment merely because the rule promulgated by the agency,” or its supporting analyses, “differ[] from the rule it proposed.” *Int’l Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 632 (D.C. Cir. 1973). Indeed, “if it were not possible for an agency to reexamine and even modify the proposed rule, there would be little point in the comment procedures.” *City of Stoughton*, 858 F.2d at 753. Thus, an agency may solicit comment on an aspect of its proposal and then incorporate relevant new studies or analyses in response without restarting the notice and comment process so long as the changes are not “so major” the proposal fails to frame the “subjects for discussion.” *Id.* (finding no violation where final CERCLA rule incorporated additional new studies and analyses after comment that ultimately confirmed the same underlying decision as the proposed rule); *Int’l Fabricare Inst.*, 972 F.2d at 399 (holding that EPA’s reliance on new studies, incorporated in response to comments, did not require re-opening of comment period).

Here, EPA provided Petitioners “fair notice of, and full opportunity to comment on, the issue actually decided by the EPA.” *Id.*; *City of Stoughton*, 858 F.2d at 753. Far from having “no chance” to engage on the topics it outlines, Pet’rs’ Br. at 49, Petitioners “exercised [their] right on the very point[s] in question,” and “submit[ted] detailed comments on [these] issues.” *City of Stoughton* 858 F.2d at 753; *Int’l Fabricare Inst.*, 972 F.2d at 399. For example, Petitioners’ argument that EPA underestimated the number of sites that will require PFOA and PFOS remediation relies on information that Petitioner Institute for Scrap Recycling referenced in its public comments. *Compare* Pet’rs’ Br. at 58-59, 72 (estimating more than 57,000 sites with projected PFOA or PFOS contamination) *with* Institute for Scrap Recycling Comments, EPA-HQ-OLEM-2019-0341-0556 at 4, JA____ (same). Petitioners’ argument that EPA underestimated the costs of remediation at non-federal Superfund Sites relies on a Chamber of Commerce Cost Analysis that multiple Petitioners submitted or referenced during the comment period. *Compare* Petr’s’ Br. at 10, 56 *with* ACC Comm. at 7, JA____; AGC Comm. at 7, JA____; Chamber Comm. at 49, JA____. Petitioners’ argument that EPA failed to account for the costs of CERCLA liability and associated operational disruptions also echoes claims made in their public comments. *See* NWRA Comm. at 3-4, JA____ - ____; ACC Comm. at 4-6, 18 n.56, JA____ - __, ____; Chamber Comm. at 15-17, JA____ - __; Petr’s’ Br. at 59, 63-67. Indeed, Petitioners’ challenges to EPA’s cost

analysis largely repeat arguments they made in their comments. *Compare* Comment Responses at 289, JA_____ with Petr’s’ Br. at 52, 55-56, 59.

EPA’s final rule responded to Petitioners’ arguments and presented further data that confirmed the conclusions in EPA’s proposed designations. Comment Responses at 222, 289, 302-05, JA_____, _____, _____ - ____; 89 Fed. Reg. at 39,149, JA_____. Though any new information would give Petitioners a “different proposition against which to argue,” Petitioners have not “shown ... that the content of their criticisms would have been different to the point that they would have stood a better chance of convincing the Agency.” *United Steelworkers of Am., AFL-CIO-CLC v. Marshall*, 647 F.2d 1189, 1225 (D.C. Cir. 1980) (citation omitted); *see also U.S. Telecom Ass’n v. FCC*, 825 F.3d 674 (D.C. Cir. 2016). At bottom, Petitioners’ problem is “not that [they] could not make comments but simply that EPA did not agree with [their] comments.” *City of Stoughton*, 858 F.2d at 753.

Petitioners’ notice arguments also fail because, as this Court has consistently held, agencies need not solicit comment on materials that are not “critical to” the determination and merely “confirm[] the findings delineated in the proposal.” *See Bldg. Indus. Ass’n v. Norton*, 247 F.3d 1241, 1246 (D.C. Cir. 2001); *Int’l Fabricare*, 972 F.2d at 399; *Competitive Enter. Inst. v. Dep’t of Transp.*, 863 F.3d 911, 920 (D.C. Cir. 2017) (holding that an agency does not violate notice and comment

requirements by “includ[ing] new ‘supplementary’ information that ‘expands on and confirms’ data in the rulemaking record.”). The authorities cited by Petitioners affirm this principle. *See Owner-Operator Indep. Drivers Ass’n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 201 (D.C. Cir. 2007) (requiring comment on revisions that are “unquestionably among ‘the most critical factual material ... used to support the agency's position’”).

Here, the estimates added to EPA’s cost analysis are not critical to the Hazardous Substance Designations. CERCLA does not require EPA to consider costs when designating hazardous substances, which is legally justified solely on the basis of EPA’s finding that PFOA and PFOS “may present substantial danger to the public health or welfare or the environment.” *See supra* pp. 25-31; 89 Fed. Reg. at 39,131, JA _____. To the extent EPA had to consider costs, the Economic Assessment did so. *See supra* pp. 32. The “illustrative” estimates added in the Regulatory Impact Analysis merely “confirmed the findings delineated in the proposal.” *Bldg. Indus. Ass’n*, 247 F.3d at 1246; 89 Fed. Reg. at 39,126; 39,179; 39,181, JA ____, ____, _____. However, as EPA made clear, it would have reached the exact same outcome and finalized the Hazardous Substance Designations “even without consideration of” quantified costs and benefits. 89 Fed. Reg. at 39,131, 39,155, JA ____, ____.

2. EPA’s assessment of the designations’ costs was not arbitrary or capricious

In its Regulatory Impact Analysis, EPA acknowledged “uncertainties

regarding costs, benefits, and potential transfers associated with response actions for PFOA/PFOS contamination.” RIA at 214, JA____. Given the highly contingent nature of those impacts and limited data at the threshold stage of designation, EPA used clear and methodologically sound assumptions to provide estimates of a range of indirect costs and benefits. *E.g.*, EPA Br. at 60-61 (explaining that, due to constraints on government resources, EPA will be able to take enforcement action at some but not all federal Superfund sites with PFOA or PFOS contamination); EPA Br. at 57-60 (explaining that PFOS and PFOA are frequently co-located with other hazardous substances); EPA Br. at 54-56 (explaining that EPA has the authority to remediate PFOA and PFOS without the hazardous substance designations, as it has already begun to do).

Petitioners take issue with EPA’s assumptions and push this Court to credit their cost estimates over EPA’s. *See* Pet’rs’ Brief at 52-68. However, under the controlling standard of review, EPA has “discretion to arrive at a cost figure within a broad zone of reasonable estimate.” *Nat’l Wildlife Fed’n*, 286 F.3d at 563; *Cigar Ass’n of Am.*, 5 F.4th at 76. In its brief, EPA explains the basis for its cost assumptions, as well as the flaws in Petitioners’ critiques. EPA Br. at 53-67. Indeed, as EPA explains, many of Petitioners’ arguments are predicated on a misunderstanding of EPA’s cost analysis and of applicable legal requirements. *Id.* Ultimately, EPA’s well-reasoned cost analyses lie well within a “broad zone of

reasonable estimate.” *Nat'l Wildlife Fed'n*, 286 F.3d at 563. Intervenor concurs with and adopt EPA’s arguments regarding its cost analysis and add the following points.

First, Petitioners argue it was arbitrary for EPA to label the transfer of costs from the public to potentially responsible parties as an advantage of designation. Pet’rs’ Br. at 53, 56-57. Petitioners’ true argument is not with EPA but with Congress, which established the “two ... main purposes of CERCLA”: (1) “prompt cleanup of hazardous waste sites” and (2) “imposition of all cleanup costs on the responsible party.” *Meghrig v. KFC W.*, 516 U.S. 479, 483 (1996) (citation omitted); *see also* H.R. Rep. No 99-253 at 55 (1985) (“[I]t is clear from the accumulating data on waste sites that EPA will never have adequate monies or manpower to address the problem itself. As a result, an underlying principle ... is that Congress must facilitate cleanups ... by the responsible parties.”). It does not “warp[] EPA’s incentives” to transfer costs to responsible parties or enable the government to take on more remediation than it otherwise could have. Pet’rs’ Br. at 54. Indeed, that is one of the “central objective[s]” of CERCLA. 89 Fed. Reg. at 39,152, JA____.⁹

⁹ *See also* 89 Fed. Reg. 39,149 n.42, JA____ (explaining that EO 12866 does “not determine the appropriate consideration of advantages and disadvantages for EPA final actions. Instead,...CERCLA[] must be evaluated to determine the intended benefits of the statute as determined by it [sic] terms.”).

Petitioners instead create a strawman, outlining a hypothetical in which EPA blithely double-counts quantified benefits and defines costs out of existence. Pet'rs' Br. at 57. The reason Petitioners rely on a hypothetical for this double-counting argument, as opposed to citing the Regulatory Impact Analysis or the rule, is because EPA never actually performed the summation they describe. *See id.* (lacking record citation). In its Regulatory Impact Assessment, EPA acknowledges that remediation of PFOA and PFOS will impose costs on potentially responsible parties, generate health benefits, and advance CERCLA's purpose of transferring the remedial obligations to responsible parties. 89 Fed. Reg. at 39,164, JA____. But EPA never sums the total amount of health benefits and transfers, nor does EPA calculate the "net benefits" of site remediation, as Petitioners suggest. Pet'rs' Br. at 57. Instead, EPA independently analyzed remedial costs and public benefits and accurately described the transfer of cleanup responsibility to potentially responsible parties as an advantage under CERCLA. 89 Fed. Reg. at 39,164, JA____. This approach is not arbitrary or capricious.

Petitioners erroneously claim, without citation, that EPA "assumed [site] cleanup would occur only where EPA takes enforcement action." Pet'rs' Br. at 59. This assertion is incorrect. EPA recognized that site cleanup can occur under a

variety of authorities, including state action. RIA at 67 n.81, JA _____. EPA discusses these authorities qualitatively. *Id.* at 89, 159-60, JA ____, ____ - __. And, given the greater certainty about its own actions, EPA provided a quantitative estimate for cleanup actions it controls. *Id.*; *see also* EPA Br. at 60-61.

Beyond their challenges to EPA's cost analysis methodology, Petitioners argue that EPA failed to respond to a battery of sector-specific complaints related to potential CERCLA liability and other costs Petitioners misattribute to the Hazardous Substance Designation. Petr's' Br. at 63-68. But Petitioners "cite no authority for the proposition that [EPA] needed to consider [costs] ... specifically for each industry." *Cigar Ass'n of Am.*, 5 F.4th at 76; *Huntco Pawn Holdings v. Dep't of Def.*, 240 F. Supp. 3d 206, 220-221 (D.D.C. 2016). EPA's rule and comment responses extensively discuss the designations' costs, including an explanation that CERCLA liability is not imposed by the designations themselves but is rather contingent upon subsequent actions and decisions. EPA Br. at 62-64; 89 Fed. Reg. at 39,129-30, 39,179-80, JA ____ - __, ____ - __; Comment Responses at 222, 268-70, JA ____, ____ - __. There is nothing in the sector-specific comments that distinguishes their liability and cost arguments from those that EPA repeatedly addressed in its comment responses.

EPA's comment responses more than satisfy the agency's obligations under the APA. While agencies must respond to "major substantive comments," "nothing

in the APA saddles agencies with the crushing task of responding to every single example cited.” *Env’t. Def. Fund v. EPA*, 922 F.3d 446, 458 (D.C. Cir. 2019).

Moreover, “[t]he failure to respond to comments is significant only insofar as it demonstrates that the agency’s decision was not ‘based on a consideration of the relevant factors.’” *Huntco*, 240 F. Supp. 3d at 219. That is not the case here.

Petitioners do not demonstrate that EPA’s designation of PFOA and PFOS was not based on the relevant factors. To the contrary, their comments relate to speculative costs that are not caused by or relevant to the Hazardous Substance Designations, as EPA explained in its responses to other comments.¹⁰

3. EPA correctly certified that the designations’ direct impacts do not require further review under the Regulatory Flexibility Act

EPA rationally certified that the Hazardous Substance Designations will not “have a significant economic impact on a substantial number of small entities,” and thus did not require further review under the Regulatory Flexibility Act (“RFA”). 5 U.S.C. § 605(b); 89 Fed. Reg. at 39,184, JA _____. Petitioners acknowledge that only the “direct impacts” of a rule must be considered under the RFA, but they

¹⁰ Contrary to Petitioners’ claim, the omission of construction contractors from the rule’s list of potentially affected entities does not constitute a notice violation. Pet’rs’ Br. at 65-66. That list was, by its terms, “not intended to be exhaustive.” 89 Fed. Reg. at 39,132, JA _____. Moreover, EPA’s listing of other “industries ... [that are] representative of potential future construction sites,” including “airports, industrial mills, manufacturing facilities, and plants—as well as agricultural land,” put the nation’s “leading association for the construction industry” on notice of the potential impacts on contractors. AGC Comm. at 1-3, JA ____ - ____.

misinterpret that term to cover *any* impact felt by entities that are subject to the rule, no matter how attenuated or speculative. Pet'rs' Br. at 70-71. Petitioners' interpretation is unsupported by case law and contradicted by the RFA's plain text.

As courts within this Circuit have made clear, “the RFA calls for agencies to scrutinize only the regulations’ direct impact, such as ‘reporting, recordkeeping and other compliance requirements’—not indirect impacts caused by the actions of third parties.” *Fla. Bankers Ass’n v. Dep’t of Treasury*, 19 F. Supp. 3d 111, 126 (D.D.C. 2014), *vacated on other grounds* 799 F.3d 1065 (D.C. Cir. 2015) (citing 5 U.S.C. § 604(a)(5)); *Am. Trucking Ass’ns v. EPA*, 175 F.3d 1027, 1044 (D.C. Cir. 1999) (holding that economic impacts of Clean Air Act standards on small entities did not include indirect costs associated with state implementation of those standards). In its RFA certification, EPA appropriately considered the direct impacts of the Hazardous Substance Designations, such as PFOA and PFOS release reporting requirements, and “not indirect impacts,” such as litigation and cleanup costs, “caused by the actions of third parties.” *Fla. Bankers Ass’n*, 19 F. Supp. 3d at 126; *see also* 89 Fed. Reg. at 39,128 n.9, JA _____. EPA’s interpretation aligns with the ordinary understanding of “direct impacts” as those that “follow[] as an immediate consequence of the” challenged activity. *Republic of Arg. v. Weltover*, 504 U.S. 607, 618 (1992) (defining “direct effects” under the Foreign Sovereign Immunities Act) (cleaned up).

Petitioners' reliance on *Mid-Tex Elec. Co-op. v. FERC* is inapposite. 773 F.2d 327, 341 (D.C. Cir. 1985); Pet'rs' Br. at 70-71. In *Mid-Tex*, this Court ruled that an agency does not need to prepare an RFA analysis for impacts to entities the rule does not regulate, such as wholesale customers buying from the utilities directly regulated by the rule. *Id.* at 341-42. *Mid-Tex* does not hold the converse—that any cost, no matter how contingent or remote, must be analyzed under the RFA as long as it is incurred by a regulated entity. *See* Pet'rs' Br. at 71. Indeed, Petitioners' suggestion that any cost to a regulated entity is a direct cost would require agencies to conduct increasingly speculative economic analyses with no clear endpoint, imposing an unworkable burden. EPA's determination of what is encompassed in direct costs is reasonable and well within the bounds of relevant precedent and statutory text.

III. EPA Appropriately Acknowledged and Addressed the Uncertainties Related to the Hazardous Substance Designations

Finally, Petitioners claim that the Hazardous Substance Designations were arbitrary and capricious because of EPA's "acknowledg[ed] ... uncertainty as to the consequences of that action." Pet'rs' Br. at 72. EPA's forthright acknowledgment of uncertainty is a reason to uphold the designations, not to overturn them.

First, the attenuated and speculative downstream economic effects of designating PFOA and PFOS are irrelevant to CERCLA's standard for designating hazardous substances. *See supra* pp. 25-31. It would have been arbitrary and

beyond statutory authority for EPA to decide *not* to designate PFOA and PFOS, two ubiquitous chemicals that pose profound health risks, because it could not determine with certainty, for example, the “unintended consequences ... on real estate transactions.” Pet’rs’ Br. at 72; *see generally Nat. Res. Def. Council v. EPA*, 529 F.3d 1077, 1085 (D.C. Cir. 2008) (“EPA acknowledged that the data was not comprehensive, but compensated for this uncertainty by erring on the side of protecting public health. We think that is a reasonable position.”).

Further, as this Court has recognized, “virtually every decision must be made under some uncertainty.” *U.S. Dep’t of Interior v. FERC*, 952 F.2d 538, 546 (D.C. Cir. 1992). That is particularly so here, where the impacts at issue depend on a string of decisions involving unknown sites and parties that may, or may not, transpire years in the future. Where an agency “must make predictive judgments about the effects” of its actions, judicial review “is limited,” “requir[ing] only that the agency acknowledge factual uncertainties and identify the considerations it found persuasive.” *Rural Cellular Ass’n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009); *see also Mexichem Specialty Resins v. EPA*, 787 F.3d 544, 560-61 (D.C. Cir. 2015) (“If EPA were required to gather exhaustive data about a problem for which gathering such data is not yet feasible, the agency would be unable to act even if such inaction had potentially significant consequences.”).

Petitioners rely on *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079 (D.C. Cir. 2014), for the position that “at some point, action infected by enough uncertainty cannot be called reasoned.” Pet’rs’ Br. at 72. They omit the following sentence: “Distinguishing among these degrees [of uncertainty] is *emphatically the province of EPA*.” *Ctr. for Biological Diversity*, 749 F.3d at 1090 (emphasis added) (upholding EPA decision not to regulate). Here, EPA made reasonable projections based on available information, acknowledged areas of uncertainty, and identified the considerations it relied upon.

Petitioners note that “EPA admits uncertainty as to where PFOA and PFOS are located, and in what quantities.” Pet’rs’ Br. at 73. But CERCLA does not require EPA to delineate the full extent of a chemical’s contamination before listing it as a hazardous substance, a bar that would preclude virtually any hazardous substance designation. *See* 42 U.S.C. § 9602(a). Here, EPA found that “PFOA and PFOS have been detected in the drinking water of millions of Americans and are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States.” 89 Fed. Reg. at 39,163, JA____; *see also id.* at 39,148, JA____ (“PFOA and PFOS have been detected in surface and subsurface soils.”). EPA disclosed the proportion of federal Superfund sites with known PFOA and PFOS contamination and estimated the number of sites where available data indicate the potential for future PFOA and PFOS enforcement actions. RIA at 20,

160-61, JA____, ____ - _____. Because there is no comprehensive list of PFOA- and PFOS-contaminated sites, and not all sites with such contamination will be remediated under CERCLA, EPA appropriately acknowledged “uncertainty concerning the location and number of sites that will be identified as needing remediation and the extent of contamination at those sites.” 89 Fed. Reg. 39,150, JA____. The Hazardous Substance Designations will help to fill that gap by requiring the reporting of PFOA and PFOS releases and promoting the investigation of potentially contaminated sites. *Id.* at 39,151, JA_____.

Nor do “uncertain[ies] about ... economic costs” preclude the Hazardous Substance designations. Pet’rs’ Br. at 74. As described above, although CERCLA section 102 does not require consideration of costs, EPA nonetheless evaluated the direct and indirect costs of the Hazardous Substance Designations in its proposed and final rules. *See supra* pp. 31-33. Many of the costs that Petitioners complain of—“response costs, costs that may arise from a judgment of liability, and litigation costs,” Pet’rs’ Br. at 74 (citation omitted)—require speculation about potential decisions in future litigation involving unknown parties and an untold number of unidentified sites. EPA’s “decision not to include those costs deemed too uncertain or speculative in the total potential incremental cost of the designation[s] was within its discretion ... [and] not arbitrary and capricious.” *Alaska Oil & Gas Ass’n v. Jewell*, 815 F.3d 544, 565 (9th Cir. 2016).

Petitioners' claim that EPA "lacks certainty as to *how* parties should address [PFOA and PFOS] contamination" is similarly misplaced. Pet'rs' Br. at 75 (emphasis in original). CERCLA does not require EPA to evaluate remedial options and technologies when designating hazardous substances, much less to predetermine which technologies should be used. Rather, that analysis is part of the separate, and subsequent, remedy selection for each site. In 2024, EPA updated its *Interim Guidance on the Destruction and Disposal of PFAS and Materials Containing PFAS*, which it referenced in the Hazardous Substance Designations. 89 Fed. Reg. at 39,129, JA____. Parties can draw upon that guidance when making site-specific remedial decisions.

Finally, Petitioners falsely claim that EPA "cannot foresee the unintended consequences of its actions," such as "hamper[ed] real estate transactions" and the "diver[sion of] resources from more urgent cleanup sites." Pet'rs' Br. at 75-76. EPA evaluated those alleged impacts and found them speculative and not reasonably attributable to the Hazardous Substance Designations. *See, e.g.*, Comment Responses at 186, JA____. For instance, while the Hazardous Substance Designations do not require any PFOA and PFOS investigations, Petitioners argue prospective purchasers of potentially contaminated property will voluntarily conduct such investigations to limit their potential CERCLA liability, and that such investigation will complicate the transaction. Even if environmental diligence and

knowledge of potential contamination could be construed as a cost, environmental site investigations are already “a common feature of real estate transactions.” See Rose-Marie T. Carlisle & Laura C. Johnson, *The Impact of CERCLA on Real Estate Transactions*, 4 S.C. Env’t. L. J. 129 (1995). Further, the discovery of PFOA or PFOS contamination can impact real estate transactions with or without the Hazardous Substance Designations. To the extent the designations increase the number or expand the scope of such investigations, EPA acknowledged that possibility and explained various steps the agency has taken to protect “innocent landowners” who purchase contaminated property from CERCLA liability. Comment Responses at 194-95, JA____-__.

CONCLUSION

For the foregoing reasons, as well as those stated in EPA’s brief, the Court should deny the petitions for review.

Dated: February 13, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

Counsel hereby certifies, in accordance with Federal Rule of Appellate Procedure 32(g)(1), that the foregoing brief contains 10,995 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f), as counted by counsel's word processing system, and thus complies with the 11,050-word limit established in the Court's October 1, 2024, order.

Further, this document complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 using size 14 Times New Roman font. *See* Fed. R. App. P. 32(a)(5), (6).

Dated: February 13, 2025

/s/ Jonathan Kalmuss-Katz
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the accompanying **PROOF BRIEF OF INTERVENOR-RESPONDENTS** with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on February 13, 2025.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: February 13, 2025

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